#### IN THE UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF PENNSYLVANIA

LARRY G. JUNKER,	)	
Plaintiff,	) )	Case No. 2:13-cv-4606-MSG
v.	)	
MEDICAL COMPONENTS, INC. and,	)	
MARTECH MEDICAL PRODUCTS, INC.	)	
Defendants.	)	
Defendants.	,	

<u>DEFENDANTS MEDICAL COMPONENTS, INC. AND MARTECH MEDICAL PRODUCTS, INC.'S RESPONSIVE BRIEF ON CLAIM CONSTRUCTION</u>

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#### I. INTRODUCTION

Defendants Medical Components, Inc. and Martech Medical Products, Inc. (collectively, "MedComp") hereby submit their responsive brief on claim construction of the single claim of United States Design Patent No. D450,839 ("the D'839 patent") in accordance with the Court's Order of January 30, 2017 [ECF 178].

# A. D'839 Patent Is Invalid Because The Design Elements Are Illustrated Differently In The Figures, Which Makes The Ornamental Appearance Of The Claimed Design Indefinite

In claim construction, the U.S. Supreme Court has said that the trial court must evaluate the D'839 patent to construe the claim of this patent on its own because claim construction is a matter of law, not fact, and not a matter for a jury. *Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 372 (1996). If the scope of the claim is not reasonably certain, the Court can also find the claim indefinite under 35 U.S.C. § 112 based on the same inconsistencies that require claim construction. *Natuilus, Inc. v. Biosig Instruments, Inc.* 134 S.Ct. 2120, 2129 (2014).

Accordingly, the Court must consider the definite nature of the claim during claim construction. *See Young*, 492 F.3d at 1346. If a claim is found to be indefinite, then claim construction is no longer needed because the claim is indefinite and thus invalid. *Times Three Clothier, LLC v. Spanx, Inc.* 2014 WL, 1688130 at \*9 (S.D.N.Y. Apr. 29, 2014).

The D'839 patent has one claim and nine figures filed as a single design for a "handle for introducer sheath" (D'839 Patent quoting the title, the claim, and the description of FIG. 1). This means the claim can have just one, and only one, unambiguous and consistent design, where the lines and contours of the elements connect to each other, and are the same elements from figure to figure. However, following a careful review of Figures 1-9, as the Court is required to do, the Court will find numerous different, inconsistent, and ambiguous design elements that contradict

each other. These ambiguities and contradictions render the claimed design indefinite as a whole, and in part, to such a degree to render the claim incapable of construction as the scope of the claim is not reasonably certain. *See Young v. Lumenis, Inc.*, 492 F.3d 1336, 1346 (Fed. Cir. 2007) ("Claims are considered indefinite when they are not amenable to construction....Thus, the definiteness of claim terms depends on whether those terms can be given any reasonable meaning" (internal citations omitted)). As a matter of law, such ambiguity creates uncertainty and violates the essence of patent law. *See id*. The inconsistencies that make the scope of the claim unclear, include:

#### **Table Of Inconsistencies**

Figures 1-2 illustrate the tops of the "ears" with	Figures 3-6 and 8 illustrate the tops of the
5 ribs	"ears" with six ribs
Figure 8 illustrates the design as not including	Figures 1-4, 5 and 9 illustrate the "scallop"
a "scallop" feature in the tops of the ears	feature as being present
Figures 4, 7 and 8 illustrate a steep angle (62°)	Figures 3 and 6 illustrate the ears as being
of the "ears" being upswept	upswept at a substantially shallower angle
	(38°)
Figures 1-3, and 5-6 illustrate a hub that	Figures 4, and 8-9 illustrate the V-notch of the
contains V-notches with two steps	hub as not having a second step
Figures 1-2 and 5 illustrate the second step of	Figures 3 and 6 illustrate the second step of the
the V-notch at the base of the hub	V-notch at an elevation that is perceptibly
	higher than the base of the hub

Based on the drawings and text of the D'839 patent, a person of skill in the art and an ordinary observer are unable to reasonably ascertain what the scope of the claim is. The Court does not have to go any further with a claim construction beyond making the legal conclusion that the claim is indefinite, which will strike the D'839 patent down as invalid. *Eclectic Products, Inc. v. Painters Products, Inc.*, 2015 WL 930045, \*3 (D. Oregon Mar. 2, 2015). This is a determination that is strictly within the Court's discretion. *Id.* 

<sup>&</sup>lt;sup>1</sup> **Ex. 1**, Expert Report of Richard P. Meyst, ¶¶ 101-106 (SJM0001150-1156 of ECF 94-79)

B. D'839 Patent Drawings Are Inconsistent Because Junker Did Not Invent The Design Elements. He Took A Set Of Drawings From Eddings And Filed The Design Patent Application Based On Those Drawings Without The Authorization Of Eddings And Gilespie

All of the design elements of the introducer shown in the drawings of the D'839 patent were invented by James Eddings and Richard Gillespie.<sup>2</sup> But, Plaintiff Larry G. Junker ("Junker") contends that he invented one element of the claimed design, the enlarged rounded portions of the introducer's handle.<sup>3</sup> Junker filed the application without the authorization or permission of Eddings or Gillespie based on drawings of the introducer he received from them.<sup>4</sup> Junker failed to notice that the drawings inconsistently illustrated several different design features across multiple figures because he was not the inventor of these elements.<sup>5</sup>

C. To The Extent The Court Finds It Can Construe The Claim, The Claim Must Be Construed To Include All The Ornamental Features Shown In Solid Line In The Drawings. It Cannot Be Construed As Only Requiring "Mickey Mouse Shaped Ears" In An Upswept Configuration As Proposed By Junker

To the extent the Court finds that the claim is sufficiently clear such that the scope of the claim can be reasonably understood, Defendants respectfully submit that a formal construction relating to the actual scope of the claims of the D'839 patent be provided that requires the scope of the claim to include the overall ornamentation of the design shown in solid line in all of the drawings of the D'839 patent. The claim cannot be construed to include just one element and then ignore all other elements shown in solid line as all elements form part of the claimed design.

<sup>&</sup>lt;sup>2</sup> Ex. 2, James Eddings Depo. Transcript, at 46:2 to 50:5, 108:5-109:14; Ex. 3, Richard Gillespie Depo. Transcript, at 26:6 to 37:20, 42:11-46:18, 50:6-15, 64:6-65:7, 69:3-72:5, 76:2-78:11

<sup>&</sup>lt;sup>3</sup> Ex. 4, Junker Depo. Transcript, at 42:23-44:24, 58:6-9, 89:2-96:2

<sup>&</sup>lt;sup>4</sup> Ex. 2, at 48:2-17, 50:10-15, 108:5-109:14; Ex. 3, at 31:4-32:14, 42:6-44:18, 69:7-71:1

<sup>&</sup>lt;sup>5</sup> **Ex. 2**, at 46:2 to 50:5, 108:5-109:14; **Ex. 3**, at 26:6 to 37:20, 42:11-46:18, 50:6-15, 64:6-65:7, 69:3-72:5, 76:2-78:11; **Ex. 4**, at 42:23-44:24, 58:6-9, 89:2-96:2; **Ex. 1**, ¶¶ 101-113 & 155-161 (SJM0001150-1158 and SJM00011779-1182 of ECF 94-79); **Ex. 5**, Expert Report of Gerald J. Mossinghoff, at ¶¶ 39-41,46, 48, and 57

Sport Dimension, Inc. v. Coleman Co., Inc., 820 F.3d 1316, 1322-23 (Fed. Cir. 2016). Plaintiff proposes to eliminate all "structural elements from the claim", which improperly converts "the claim scope of the design patent from one that covers the overall ornamentation to one that covers individual elements". Id. The overall ornamentation of the design must be included within the scope of the claim even for the structural elements that serve a functional purpose "so that the fact finder should not focus on the particular designs of these elements when determining infringement, but rather focus on what these elements contribute to the design's overall ornamentation." Id.

#### II. CLAIM CONSTRUCTION STANDARD

Claim construction is a matter of law solely for the court. *Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 372 (1996). The purpose of claim construction is to resolve disputes between the parties about the scope of the patent claim. Accordingly, claim construction in design patent cases is required before invalidity or infringement can be determined. *Egyptian Goddess, Inc. v. Swisa, Inc.*, 543 F.3d 665, 679-80 (Fed. Cir. 2008).

If the meaning of the claim is clear from the intrinsic evidence alone, resort to extrinsic evidence is improper. *Boss Control, Inc. v. Bombardier Inc.*, 410 F.3d 1372, 1377 (Fed. Cir. 2005). If the meaning is not clear form only the intrinsic evidence, a court may consider extrinsic evidence, such as expert and inventor testimony, dictionaries, and treatises even though such extrinsic evidence is "generally of less significance than the intrinsic record." *Takeda Pharma. Co. Ltd. v. Zydus Pharma. USA, Inc.*, 743 F.3d 1359, 1363 (Fed. Cir. 2014).

The construction of design patents presents a special challenge to courts, as design patents are often "claimed as shown in drawings, and claim construction must be adapted to a pictorial setting." *Crocs, Inc. v. Int'l Trade Comm'n*, 598 F.3d 1294, 1302 (Fed. Cir. 2010). "In order to derive a claim construction, the design features of the claim must

be definite, consistent, and unambiguous as a matter of law and public policy so the ordinary observer knows what is claimed. *Times Three Clothier, LLC v. Spanx, Inc.*, 2014 WL 1688130 at \*6-8 (S.D.N.Y., April 29, 2014). A skilled artisan examining the D'839 patent must be able to reasonably ascertain "what exactly the inventor intended to claim." *Eclectic Products, Inc. v. Painters Products, Inc.*, 2015 WL 930045, \*3 (D. Oregon Mar. 2, 2015). A claim cannot be construed if it has inconsistent and ambiguous claimed design features. *Id.* 

In Egyptian Goddess, Inc. v. Swisa, Inc., 543 F.3d 665, 680 (Fed. Cir. 2008) (en banc), the Federal Circuit stated: "[a]part from attempting to provide a verbal description of the design, a trial court can usefully guide the finder of fact by addressing a number of issues that bear on the scope of the claim." Id. The Federal Circuit has provided three issues that bear on the scope of the claim: 1) describing the role of particular conventions in design patent drafting, such as the role of broken lines; 2) assessing and describing the effect of any representations made in the course of the prosecution history; and 3) distinguishing between those features of the claimed design that are ornamental and those that are purely functional. Id. (citing OddzOn Prods., Inc. v. Just Toys, Inc., 122 F.3d 1396, 1405 (Fed. Cir. 1997)).

### A. Indefiniteness Of The Claim Should Be Assessed At Claim Construction

"Indefiniteness is a matter of claim construction" and, therefore, a question of law *Praxair, Inc. v. ATMI, Inc.*, 543 F.3d 1306, 1319 (Fed. Cir. 2008). "Indefiniteness is a matter of claim construction, and the same principles that generally govern claim construction are applicable to determining whether allegedly indefinite claim language is subject to construction." *Datamize, LLC v. Plumtree Software, Inc.*, 417 F.3d 1342, 1348 (Fed. Cir. 2005).

The definiteness requirement applies to design patents as well as utility patents. *See Litton Systems, Inc. v. Whirlpool Corp*, 728 F.2d 1423, 1440-41 (Fed. Cir. 1984) (overruled on

other grounds by *Egyptian Goddess, Inc. v. Swisa, Inc.*, 543 F.3d 665 (Fed. Cir. 2008)). Thus, even in design patents, "a patent is invalid for indefiniteness if its claims, read in light of the specification delineating the patent, and the prosecution history, fail to inform, with reasonable certainty, those skilled in the art about the scope of the invention." *Nautilus, Inc. v. Biosig Instruments, Inc.*, 134 S.Ct. 2120, 2120 (Sup. Ct. 2014).

Since an indefinite determination is part of claim construction, whether a claim is invalid for indefiniteness should be determined at the time the claim is construed, not after. *See Personalized Media Communications., L.L.C. v. Int'l Trade Comm'n,* 161 F.3d 696, 705 (Fed. Cir. 1998) ("A determination of claim indefiniteness is a legal conclusion that is drawn from the court's performance of its duty as the construer of patent claims."); *see also Datamize*, 417 F.3d at 1348. This is because, as part of determining the claim construction, the Court will necessarily have to determine if the claim can be construed. *See Datamize*, 417 F.3d at 1348.

### III. THE CLAIM IS INDEFINITE BECAUSE THE SCOPE OF THE CLAIM IS NOT REASONABLY CERTAIN

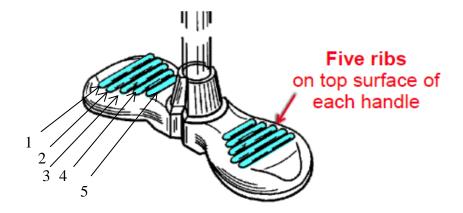
Figures 1-9 of the drawings are all purportedly illustrations of the same design. (D'839 Patent, at Description for Figures 1-9). But, critical design features of the claim are unclear due to the number of inconsistencies that affect multiple drawings of the patent that illustrate the scope of the claim. See Seed Lighting Design, 2005 WL 1868152 at \*8-9 (finding a design patent indefinite where patent drawings inconsistently illustrate the design for a lamp base); see also Times Three Clothier, 2014 WL 1688130 at \*6-8. Due to the inconsistencies and incompatibilities, the claim does not inform those skilled in the art with reasonable certainty, is indefinite, and invalid as a matter of law. See Nautilus, 134 S.Ct. at 2120.

<sup>&</sup>lt;sup>6</sup> **Ex. 1**, ¶¶ 101-113 (SJM0001150-1158 of ECF 94-79)

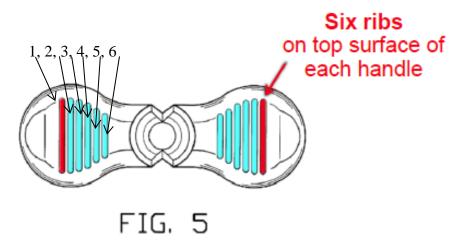
The D'839 patent consists of nine (9) separate figures, along with a specification including a brief description of the drawings and one (1) claim.<sup>7</sup> The mistakes and ambiguities in the D'839 patent claim relate to major features of the claimed design shown in the drawings: the hub, the handles and the flat, raised portion between the hub and the handles.<sup>8</sup>

The D'839 patent contains the following inconsistencies in the Figures:

### A. Figures 1 (annotated below) and 2 have <u>five ribs</u> on the top surface of each handle,



while Figures 3, 4, 5 (annotated below in red), 6, 8 and 9 have <u>six ribs</u> on the top surface of each handle;<sup>9</sup>



<sup>&</sup>lt;sup>7</sup> Ex. 6, D'893 Patent, (SJM0000419-425 of ECF 94-15), also at [ECF 182-2]

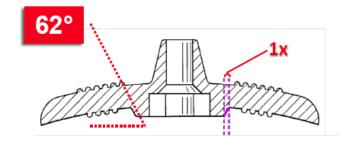
<sup>&</sup>lt;sup>8</sup> Ex. 1, ¶¶ 101-113 (SJM0001150-1158 of ECF 94-79)

<sup>&</sup>lt;sup>9</sup> Ex. 1, ¶¶ 102 (SJM0001150 of ECF 94-79)

As acknowledged by the evidence proffered by Junker in support of his claim construction, the ribs are a part of the claimed handle. (Dec. Bressler [ECF 182-6], at ¶ 41). <sup>10</sup> These ribs affect the ornamental appearance of the device as Junker admits the ribs are ornamental features of the claimed design. <sup>11</sup>

But, a person of skill in the art cannot ascertain what the ornamental appearance of the design of the handles, which are affected significantly by the presence of the ribs, is supposed to be due to the inconsistent inclusion of ribs in the drawings of the D'839 patent. In particular, Figures 1 and 2 illustrate a design in which the "Mickey Mouse" shaped handle has an appearance affected by the inclusion of 5 ribs. In contrast, Figures 3, 4, 5, and 6 show a design of such a Mickey Mouse shaped handle that has its appearance affected by the use of 6 ribs. The number of ribs that are to be included in the handle for accounting for the ornamental appearance of the design cannot be known from such differences as the number of ribs clearly affect the actual ornamental appearance of the design.

# B. Figures 4, 7 and 8 (annotated below) show a steep angle at <u>62 degrees</u> from the flat raised portion to the inner part of the wing while,

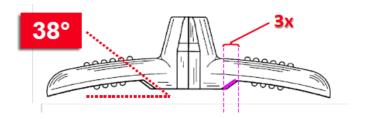


Figures 3 and 6 (annotated below) show a shallower angle at <u>38 degrees</u> from the flat raised portion to the inner part of the wing.<sup>12</sup>

<sup>&</sup>lt;sup>10</sup> **Ex. 4**, at 94:9-12

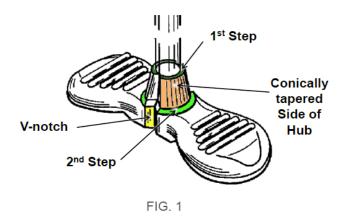
<sup>&</sup>lt;sup>11</sup> **Ex. 4**, at 94:9-12 (stating "the ribs, where they're placed in proximity to the edge would be ornamental."

<sup>&</sup>lt;sup>12</sup> **Ex. 1**, ¶ 106 (SJM0001155-1156 of ECF 94-79)

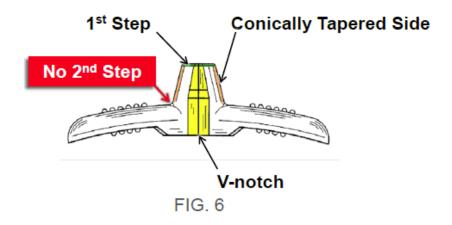


Note also that the shallower angle in Figure 6 causes the width of the angled portion to increase by <u>three times</u> the width of the same angled portion pictured in Figure 8.

C. Figures 1-3 and 5-6 illustrate a hub that <u>contains a second step</u> (annotated below in green) at the base and around the perimeter of the hub,



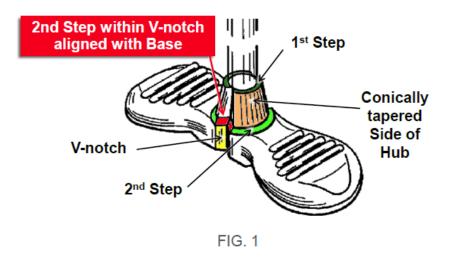
while Figures 4, 8 and 9 (annotated below) do not show a second step; 13



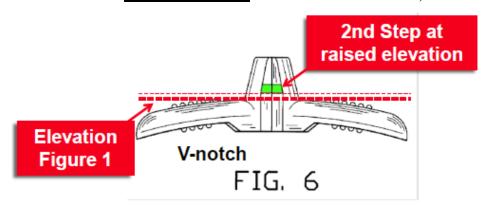
9

<sup>&</sup>lt;sup>13</sup> **Ex. 1**, ¶¶ 104-105 (SJM0001152-1154 of ECF 94-79)

D. Figures 1, 2 and 5 have a second step at the base of the hub (annotated below in red) within the V-notch,

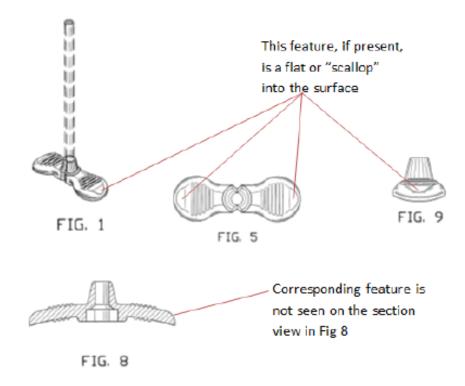


while Figures 3 and 6 (annotated below in green) have the second step at an elevation perceptibly higher than the base of the hub; <sup>14</sup>



 $<sup>^{14}</sup>$  **Ex. 1**, ¶¶ 104-105 (SJM0001152-1154 of ECF 94-79)

## E. Figures 1, 5, and 9 Provide a Scallop, whereas Figure 8 does not contain a Scallop. 15



### F. Due to the Inconsistencies In The Drawings the Claim is not Reasonably Certain

There is no way to reasonably reconcile the inconsistencies of the drawings. <sup>16</sup> A person of skill in the art cannot ascertain with certainty what the scope of the design of the claim is. For instance, a person of skill in the art cannot ascertain how many ribs are supposed to be on the top of the "Mickey Mouse" shaped ears (5 or 6?), the degree to which the "Mickey Mouse" shaped ears are to be upswept in appearance (62° or 38°?), how the hub of the design is to look (with 2 steps or just 1 step?), and whether the "Mickey Mouse" shaped ears are to include a "scallop" feature on their top surface (or not have such a feature?). These inconsistencies render the claim

<sup>&</sup>lt;sup>15</sup> **Ex. 1**, ¶ 103 (SJM0001151-1152 of ECF 94-79)

<sup>&</sup>lt;sup>16</sup> **Ex. 1**, at ¶ 116).("It is not possible to create single introducer sheath using the figures of the D'839 patent"); and id. at ¶¶ 101-106 (SJM0001150-1156 and 1158 of ECF 94-79)

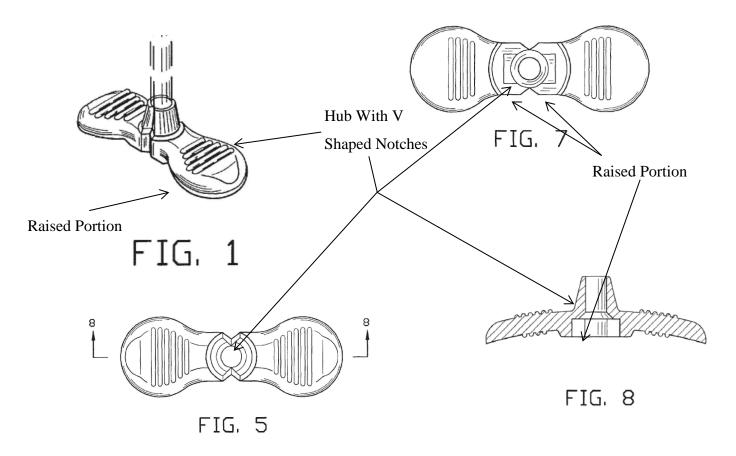
indefinite as a matter of law. *Nautilus*, 134 S.Ct. at 2120. Due to the inconsistencies in the drawings, one skilled in the art is left to speculate as to the metes and bounds of the claim. The claim of the D'839 patent therefore fails to satisfy the definiteness criteria of 35 U.S.C. § 112 and is indisputably invalid as a matter of law under that statute.

## G. The Claim Is Also Indefinite Due To Inconsistency Between The Text of The Patent And The Drawings

Junker contends that the claim is for an "ornamental design for a handle for introducer sheath, as shown in Figures 1 through 9, having two rounded ear opposing shapes with an upswept appearance." (Junker's Opening Brief [ECF 182], at 9)(emphasis added). This is based on Junker's contention that "the overall ornamental design of the handle of his invention is to the Mickey Mouse shaped ears with an upswept configuration". (*Id.* at 6). But, such a contention fails to place any limit on the scope of the claim for all the other features shown in solid line in Figures 1-9 and conflicts with the actual design of the introducer shown in Figures 1-9.

#### 1. The Design Shown In Figures 1-9 Is Not Just A Handle

As shown in the drawings of the D'839 patent and acknowledged by paragraph 42 of Peter Bressler's declaration submitted by Junker [ECF 182-6], the illustrated design shown in the drawings is not merely the "Mickey Mouse shaped ears" that have an upswept configuration. To the contrary, the design shown in solid lines as part of the claim includes the "hub", as well as other features shown in solid line. Below are Figures 1, 5, 7, and 8 all illustrating the "hub" and other features that form part of the claimed design to the "handle" in solid lines:

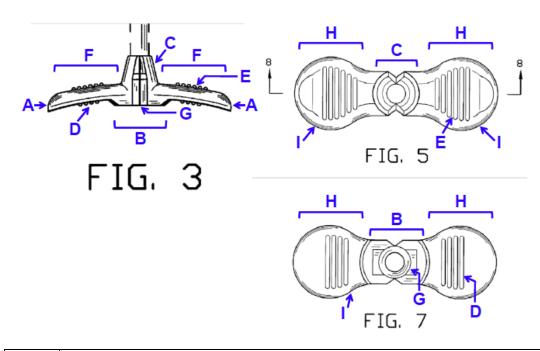


As consistently illustrated in the drawings, the hub is shown in solid line, even though it is not the alleged "Mickey Mouse Shaped ears" and is not a handle (Declaration of Peter Bressler, [ECF 182-6] at ¶ 42 (stating that "the hub that connects the handles is primarily dictated by function").

As acknowledged by Mr. Bressler in paragraph 42 of his declaration [ECF 182-6] and as contended by Plaintiff in page 6 of his opening claim construction brief [ECF 182], the "hub" is not allegedly part of the claimed handle. But, the drawings illustrate the hub in solid line. It is therefore part of the claimed design.

# 2. The Drawings Of Figures 1-9 Illustrate Other Features That Affect The Ornamental Appearance And Are Not Part Of Junker's Alleged Handle

Below are annotated Figures 3, 5, and 7 of the D'839 patent that identify all the features shown in solid line in the drawings and that form part of the claimed design:



A	Tabs (Handles) – each having pointed tip at end of bottom side and	
	rounded configuration at end of top side (see front view – Fig. 3)	
В	Flat, Raised Portion – proportional size and tapered sides (see front view	
	– Fig. 3 and bottom view – Fig. 7)	
С	Hub – having transitional steps, V-notches with internal shoulders, and	
	tapered sides (see front view – Fig. 3 and top view – Fig. 5)	
D	Rib Configuration (ridges) – bottom (see front view – Fig. 3 and bottom	
	view – Fig. 7)	
Е	Rib Configuration (ridges) – top (see front view – Fig. 3 and top view –	
	Fig. 5)	
F	Upswept Wings (Tabs) – handles downwardly arcing from center hub to	
	respective tip (see front view – Fig. 3)	
G	Rectangle, Interlocking Insert (center portion) (see bottom view – Fig. 7)	
Н	Rounded, Enlarged Handles – considering relative size, proportion,	
	roundedness of length and width (see top view – Fig. 5 and bottom view –	
	Fig. 7)	
I	Rounded Edges on Handles – different from H, above – simply that the	
	handles have no squared off corners (see top view – Fig. 5 and bottom	
	view – Fig. 7)	

### 3. The Full Design Shown In Figures 1-9 Is For An Introducer, Not Just A Handle

The words of the claim as well as Plaintiff's own contention of what the claim is to cover is to "a handle for introducer sheath". The Specification of the D'839 patent also says the drawings illustrate such a handle and the title of the patent says it is for such a handle. But, the

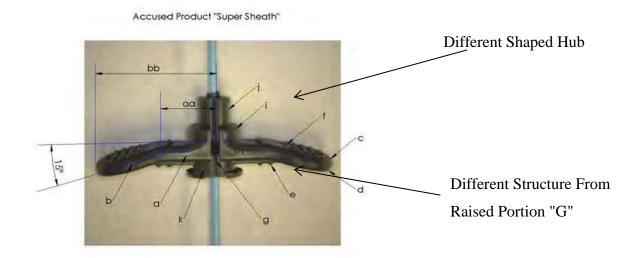
drawings of Figures 1-9 include non-handle portions, including the "hub" (identified above as element "C"), the upper flat raised portion (identified above as element "B"), and the rectangle, interlocking insert (identified above as element "G") shown in solid line in Figures 1-9. There is therefore an intractable conflict between the text of the D'839 patent and the visual description provided by the drawings. This "creates uncertainty about the claim's meaning" and renders the claim indefinite. *Eclectic Products, Inc. v. Painers Products, Inc.*, 2015 WL 930045, \*3 (D. Oregon Mar. 2, 2015)(holding a design patent claim to be indefinite because that drawings of the design patent illustrated an entire tube dispenser in conflict with the claim, which was directed to "an applicator cap".).

#### 4. The Fact That Features Shown In Solid Line May Have A Function Further Shows The Claim Is Indefinite

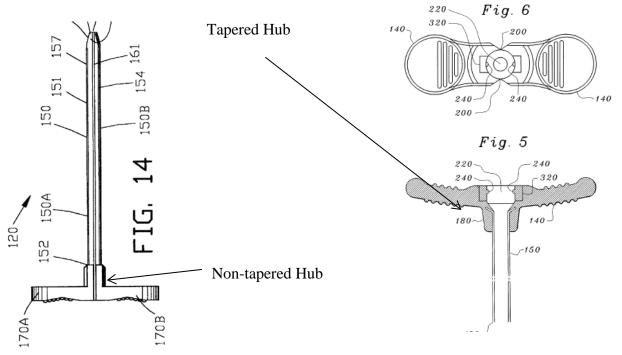
Junker alleges that the hub as well as the other portions of the design shown in Figures 1-9 of the D'839 patent that are not the "Mickey Mouse" shaped ears element are all functional and are not within the scope of the claim. (Junker's Opening Brief [ECF 182] at 2 and 7-8). Junker contends that while the Mickey Mouse ears feature "has an element of functionality" they form part of the overall design being claimed. *Id.* at 7. In contrast, Junker contends that the "central hub and hole were functional" and do not form a part of the claimed design because they are functional. *Id.* at 7 and Dec. of Peter Bressler [ECF 182-6], at ¶ 42).

This contradictory position is not supported by the drawings, which illustrate the hub and hole in solid line. *Sport Dimension, Inc. v. Coleman Co., Inc.*, 820 F.3d 1316, 1322-23 (Fed. Cir. 2016). Moreover, there is clearly more than one way to provide an appearance for such "functional" features identified by Junker as not being within the claim. The products accused of infringing the claim illustrate aesthetically different hub designs <sup>17</sup>:

<sup>&</sup>lt;sup>17</sup> **Ex. 1**, at ¶¶ 121-123 (SJM0001162-1163 of ECF 94-79)



As another example, the prior art, which includes the below introducer designs, have different shaped hubs, which was a basis by which the D'839 patent was found to be allowable: 18



Ex. 16, Figs. 6-7 of Prior Art U.S. Pat. No. 6,336,914

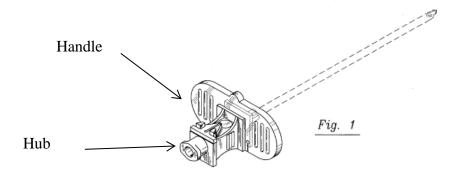
Ex. 15, Fig. 14 of Prior Art U.S. Pat. No. 6,645,178

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<sup>&</sup>lt;sup>18</sup> **Ex. 7**, Notice of Allowability mailed on Sept. 27, 2006,  $\P\P$  5-12 (SJM0001007-1010 of ECF 94-64)

5. The Evidence Shows The Handle That Junker Alleges Is The Subject Of The Claim Is Different From The Introducer Shown In Figures 1-9, Which Includes The Hub And Other Features Shown In The Solid Lines Of The Drawings

Figures 1-9 illustrate a design for an entire "introducer" that includes a "hub" and other elements as that is what is depicted in solid lines. <sup>19</sup> In addition to Junker's own contentions and the testimony of expert Richard P. Meyst, the prior art further shows that the design of Figures 1-9 includes more than just the handle. For instance, U.S. Pat. No. Des. 378,130<sup>20</sup> is for "a universal hub" as shown below, which includes a handle:



The text of the Specification of the D'839 also shows there is a conflict between the text and the drawings. As stated in the description of Figure 1 on the cover page of the D'839 patent, only the "sheath" element is "shown in phantom". The hub and other portions (e.g. the raised portion, etc.) are shown in solid line. They form part of the claimed design even though they are not the handle component of the design that Junker alleges is the entirety of the scope of the claim. (Junker's Opening Brief, at 6 [ECF 182]).

<sup>&</sup>lt;sup>19</sup> **Ex. 1**, at ¶¶ 58-65 and 116) ("It is not possible to create single introducer sheath using the figures of the D'839 patent") (SJM0001130-1134 and 1158 of ECF 94-79); **Ex. 8**, Kevin Sanford Depo. Transcript, at 99:13-15 ("the hub is comprised of the handle portion? Correct) and 151:10-154:17; **Ex. 9**, T. Schweikert Depo. Transcript, at 64:22-65:16, 68:6-19, 88:10-13 <sup>20</sup> **Ex. 10**, U.S. Pat. No. Des. 378,130 (SJM0000395-396 of ECF 94-7)

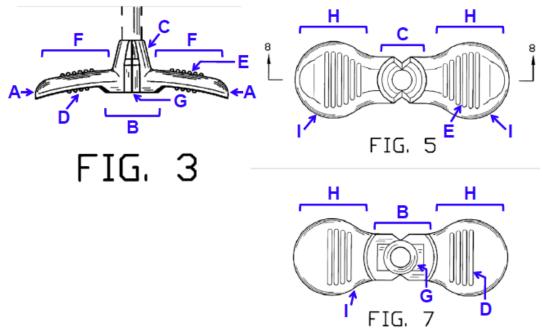
The text of the D'839 patent and Junker's allegation of what the claim of the D'839 patent's scope are in direct conflict with the visual description provided by Figures 1-9. This "creates uncertainty about the claim's meaning" and renders the claim indefinite. *Eclectic Products, Inc. v. Painers Products, Inc.*, 2015 WL 930045, \*3 (D. Oregon Mar. 2, 2015)(holding a design patent claim to be indefinite because that drawings of the design patent illustrated an entire tube dispenser in conflict with the claim, which was directed to "an applicator cap".).

# IV. IN THE EVENT THE COURT FINDS THE CLAIM TO BE DEFINITE, THE D'839 PATENT CLAIM SHOULD BE CONSTRUED TO INCLUDE ALL ELEMENTS SHOWN IN SOLID LINES

Design patents have almost no scope" and are "limited to what is shown in the application drawings." *MRC Innovations, Inc. v. Hunter Mfg., LLP*, 747 F.3d 1326, 1333 at n.1 (Fed. Cir. 2014). But, Junker has set forth argument and requested a construction that seeks to impermissibly broaden the scope of the claim by having features shown in solid lines in the drawings of the D'839 patent not included within the scope of the claim. For example, Junker has asked the Court to issue a claim construction that does not encompass the hub ("C"), raised portion ("B"), or rectangular interlocking feature ("G").

Contrary to Junker, MedComp moves for a claim construction ruling that the single claim of the D'839 patent includes all elements depicted in solid lines in the drawings in the event the Court finds that the claim is definite (which MedComp asserts it is not) as the parties dispute whether all of the structure depicted by solid lines in the figures of the design patent constitutes claimed subject matter. MedComp contends all the structure depicted in sold line in the figures form part of the claimed design and affect the ornamental appearance that is claimed, consistent with the prosecution history of the D'839 patent and the public notice function of claims. Warner-Jenkinson Co. v. Hilton Davis Chem. Co., 520 U.S. 17, 33 (1997) ("Mindful that claims do indeed serve both a definitional and a notice function ....").

The single claim of the D'839 patent recites: "The ornamental design for a handle for introducer sheath, as shown and described."<sup>21</sup> There are nine figures in the patent. While all nine figures must be considered, Figures 3, 5 and 7, showing front, top and bottom, respectively, are again set forth below and are annotated to conveniently denote names of various design features included therein, as listed below.



Pertinent Design Features of the D'839 Patent<sup>22</sup>

	1 criment Design Features of the D 0371 atent
A	Tabs (Handles) – each having pointed tip at end of bottom side and
	rounded configuration at end of top side (see front view – Fig. 3)
В	Flat, Raised Portion – proportional size and tapered sides (see front view
	– Fig. 3 and bottom view – Fig. 7)
С	Hub – having transitional steps, V-notches with internal shoulders, and
	tapered sides (see front view – Fig. 3 and top view – Fig. 5)
D	Rib Configuration (ridges) – bottom (see front view – Fig. 3 and bottom
	view – Fig. 7)
Е	Rib Configuration (ridges) – top (see front view – Fig. 3 and top view –
	Fig. 5)
F	Upswept Wings (Tabs) – handles downwardly arcing from center hub to
	respective tip (see front view – Fig. 3)
G	Rectangle, Interlocking Insert (center portion) (see bottom view – Fig. 7)

Ex. 6, at the claim [ECF 182-2] (SJM0000419 of ECF 94)
 Ex. 6, at the claim [ECF 182-2] (SJM0000419-425 of ECF 94)

Н	Rounded, Enlarged Handles – considering relative size, proportion,
	roundedness of length and width (see top view – Fig. 5 and bottom view –
	Fig. 7)
I	Rounded Edges on Handles – different from H, above – simply that the
	handles have no squared off corners (see top view – Fig. 5 and bottom
	view – Fig. 7)

As mentioned above, Junker has argued that the only ornamental element claimed in the D'839 patent is the "enlarged, rounded handles," ["H"], which Junker refers to as the "Mickey Mouse shaped ears". (Junker's Opening Brief [ECF 182] at 6). 23 "The construction proposed by Junker seeks to limit the claim to just this feature by saying that the claimed handle has "two rounded ear opposing shapes with an upswept appearance" (*Id.* at 8). This proposed construction seeks to mislead the Court and the fact finder by ignoring all the other elements shown in Figures 1-9, such as features B-I that are listed above, which are all shown in solid line and form part of the claimed design. These elements are part of the claimed design even if these elements perform a function. *Sport Dimension, Inc. v. Coleman Co., Inc.*, 820 F.3d 1316, 1322-23 (Fed. Cir. 2016).

The Federal Circuit has emphasized that the ornamental features claimed in a design patent include all of those illustrated in solid lines. Only features depicted in broken lines are excluded in determining the features claimed in the patent. "If features appearing in the figures are not desired to be claimed, the patentee is permitted to show the features in broken lines to exclude those features from the claimed design, and the failure to do so signals inclusion of the features in the claimed design." *Contessa Food Prods., Inc. v. Conagra, Inc.* 282 F.3d 1370, 1377-78 (Fed. Cir. 2002).

<sup>&</sup>lt;sup>23</sup> **Ex. 4**, at 42:23-44:24, 58:6-9, 89:2-96:2; *see also* **Ex. 2**, at 46:2 to 50:5, 108:5-109:14; **Ex. 3**, at 26:6 to 37:20, 42:11-46:18, 50:6-15, 64:6-65:7, 69:3-72:5, 76:2-78:11

Junker did not depict in dotted lines (i.e. in phantom) all the other features of the introducer shown in Figures 1-9 such that the claim was directed to only the handle itself or only to the Mickey Mouse shaped ears" component. Thus, to the extent the claim is definite, Junker "effectively limited the scope of [his] patent claim by including those features in it." *Elmer v. ICC Fabricating, Inc.*, 67 F.3d 1571, 1577 (Fed. Cir. 1995). As with *Elmer, Contessa, and Door-Master*, Junker's claim is constrained by, and includes, all of the features depicted in solid lines in the drawings. It is not just for the "Mickey Mouse shaped ears". (Junker's Opening Brief [ECF 182] at 6).<sup>24</sup>

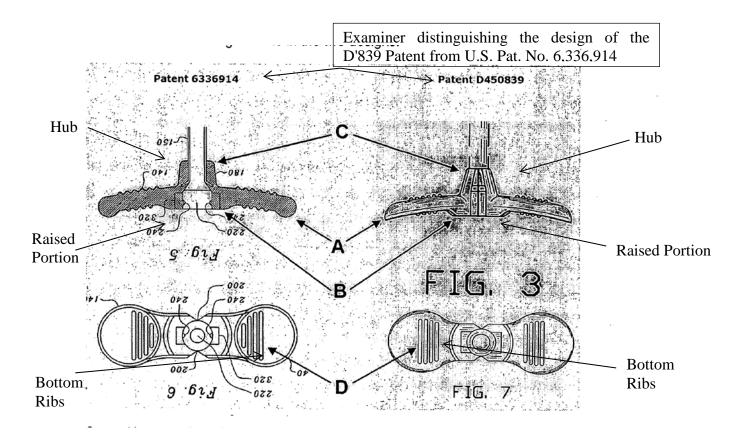
The fact that certain features shown in solid line in Figures 1-9 may have a function does not permit those features to be removed from the scope of the claim of a design patent. As acknowledged by Junker in page 7 of his Opening Claim Construction Brief [ECF 182], when there are several ways to achieve the function of an article of manufacture, the design of the article is more likely to serve a primarily ornamental purpose." *L.A. Gear v. Thom McAn Shoe Co.*, 988 F.2d 1117, 1123 (Fed. Cir. 1993); *see also American Beverage Corp. v. Diageo North America, Inc.*, 936 F.Supp.2d 555, 558 (W.D. Pa., 2013) (citing *Herbko Int'l Inc., v. Gemmy Indus. Inc.*, 916 F. Supp. 322, 326 (S.D. N.Y., 1996). Thus, all the features, even functional features, are to be considered and given weight as to how their ornamental appearance may affect the illustrated design.

### A. All The Intrinsic Evidence Shows The Claimed Design Includes More Than The "Mickey Mouse" Shaped Ears

In addition to the drawings of the D'839 patent, the prosecution history of the D'839 patent shows that the scope of the claim includes more than just the "Mickey Mouse" shaped

<sup>&</sup>lt;sup>24</sup> **Ex. 4**, at 42:23-44:24, 58:6-9, 89:2-96:2; *see also* **Ex. 2**, at 46:2 to 50:5, 108:5-109:14; **Ex. 3**, at 26:6 to 37:20, 42:11-46:18, 50:6-15, 64:6-65:7, 69:3-72:5, 76:2-78:11

ears. For instance, during a merged reissue and reexamination proceeding involving the D'839 patent, the United States Patent and Trademark Office ("USPTO") issued a Notice of Allowability mailed on September 27, 2006 articulating reasons for allowance. The reasons for allowance therein were directed, specifically, to the "substantial differences seen in the profile view of the tip portions of the tabs", "a flat portion on the side opposite the bottom side of the handle which is raised from the plane of the tabs", and the hub and the ribs shown in the drawings. For instance, page 3 of the Notice identified elements A, B, C, and D, that the Examiner found to provide a different appearance due to the "tip portions of the tabs 'A", "different rib configurations" at "D", "flat portion" at "B", and different configurations of the "hub" at "C" as identified below:



<sup>&</sup>lt;sup>25</sup> **Ex. 7**, ¶¶ 5-12 (SJM0001007-1010 of ECF 94-64)

(See also **Ex. 11**, Notice of Intent to Issue Ex Parte Reexamination Certificate mailed June 2, 2008, at page 2 setting forth the "Reasons For Confirmation" for the reexamination certificate of the D'839 patent). <sup>26</sup>

#### B. The Hub And Other Features Shown In Solid Line Have Significance To The Overall Ornamental Appearance Of The Design

Dr. Alan Cohen, who has purchased peel away sheaths from a variety of manufacturers including the ones sold by MedComp and has used peel away sheaths regularly for 30 years or more has testified that "[a]ll have different shape wings, all have different angles on the handles or wings and some have a luer lock and hemostatic valve outside the sheath which is part of the handle."<sup>27</sup> Ron Thorneberry, a registered nurse with 7 years of experience in vascular access, provided testimony that he is familiar with the considerations of what a provider looks for in tear away sheaths being purchased and that important features considered include "the hub design and the locking feature for the dilator." <sup>28</sup> Michael Anstett, a registered nurse with 7 years of experience in vascular access and 8 years as a medical device consultant testified that important features considered when purchasing tear away sheaths include "the hub design and the locking feature for the dilator." <sup>29</sup> The design of the hub and the other features shown in solid line in the drawings have a significant impact on the overall impression of the design shown in Figures 1-9 to the ordinary observer familiar with the prior art. Junker's attempt to disclaim the design of the hub as functional and assert that the "small areas" of the hub design are non-functional but insignificant are contradicted by the uncontroverted testimony of multiple ordinary observers in addition to the prosecution history of the D'839 patent.

<sup>&</sup>lt;sup>26</sup> The ex parte reexamination could not assert indefiniteness as a basis for reexamination. 35 U.S.C. § 302 (stating that reexamination requests ares only based on prior art).

<sup>&</sup>lt;sup>27</sup> Ex. 12, Declaration of Dr. Alan M. Cohen, M.D., ¶ 12 (SJM0000915 of ECF 94-49)

<sup>&</sup>lt;sup>28</sup> Ex. 13, Affidavit of Ron Throneberry, pages 1-2 ((SJM0000919-921 of ECF 94-51)

<sup>&</sup>lt;sup>29</sup> **Ex. 14**. Affidavit of Michael Anstett, pages 1-3 (SJM0000916-918 of ECF 94-50)

## C. MedComp Proposes A Construction That Requires The Claim To Include All The Ornamental Features Of The Design

The intrinsic evidence from the prosecution history of the D'839 patent shows that Junker's proposed construction is incorrect and misleading. Junker's proposed construction, which includes only the "Mickey Mouse shaped ears" feature, is directly contradicted by the construction utilized by the USPTO during examination of the patent that included all features depicted in solid lines, *i.e.*, the literal scope of the claim. *See Door-Master Corp. v. Yorktowne, Inc.*, 256 F.3d 1308, 1313 (Fed. Cir. 2001). Instead of Junker's proposed construction, the Court should adopt MedComp's proposed construction which is as follows:

The introducer sheath of the claim includes the ornamental appearance of all of the elements shown in solid line in Figures 1-9 of the D'839 patent. These features include:

- (1) the two rounded ear opposing wings that each includes (a) a scallop defined in the top surface near the tip of each wing as shown in Figures 1-2, 5, and 9, (b) a number of ribs on their top as shown in Figures 1-6 and 8-9, and (c) a number of ribs on their bottom as shown in Figures 3-4 and 6-8,
- (2) a conically tapered central hub as shown in Figures 1-9 that have V-shaped notches located between the opposed wings as shown in Figures 1-8, and
- (3) a flat extended portion having a rectangular insert on the bottom of the design between the opposed wings and aligned with the central hub as shown in Figures 1-4 and 6-8.

The sheath shown in broken lines in Figures 1-4 constitute unclaimed subject matter and are not part of the claimed design.

MedComp's proposed verbal description of the claim is aligned with, and supported by, *Egyptian Goddess* where the Federal Circuit stated: "[a]part from attempting to provide a verbal description of the design, a trial court can usefully guide the finder of fact by addressing a number of issues that bear on the scope of the claim." *Egyptian Goddess*, 543 F.3d at 680.

MedComp's proposed verbal description includes all the elements depicted in solid lines in the

D'839 patent and defines the proper scope of the claim. MedComp's proposed construction describes the role of particular conventions in design patent drafting (e.g. role of the broken lines in Figures 1-4), and distinguishes between those features of the claimed design that are ornamental and those that are purely functional by ensuring that the ornamental appearance of all the elements of the claimed design are considered.

"When the parties present a fundamental dispute regarding the scope of a claim term, it is the court's duty to resolve it." *O2 Micro Int'l Ltd. v. Beyond Innovation Tech. Co., Ltd.*, 521 F.3d 1351, 1362 (Fed. Cir. 2008). In the event the Court finds that the claim is definite (which as discussed above Defendants contend is not the case as the claim is indefinite), resolution in the present litigation is best represented by the Court exercising its discretion and attempting to translate the visual descriptions of the drawings in the D'839 patent into words that evoke the full visual image of the design to avoid the misleading impression that only the "two rounded ear opposing wings with an upswept appearance" is the scope of the claim.

#### V. CONCLUSION

MedComp respectfully requests that the Court, as a matter of law, find the claim of the D'839 patent indefinite under 35 U.S.C. § 112. In the alternative, the Court should construe the single claim of the D'839 patent to include all the elements depicted in solid lines in the patent drawings and adopt MedComp's proposed claim construction.

Respectfully Submitted,

/s/ Alfred W. Zaher

Alfred W. Zaher

Shawn Li

BUCHANAN INGERSOLL & ROONEY P. C.

Two Liberty Place, 50 S. 16th Street, Suite 3200;

Philadelphia, PA 19102-2555

Telephone: (215) 665-8700; Facsimile: (215) 665-8760

Ralph G. Fischer RALPH G. FISCHER, SBN 200793 BUCHANAN INGERSOLL & ROONEY P. C. 301 Grant Street; Pittsburgh, Pennsylvania 15219-1410 Telephone: (412) 562-1632; Facsimile: (412) 562-1041

Pro Hac Vice Attorneys for Defendants Medical Components, Inc. and Martech Medical Products, Inc.

#### **CERTIFICATE OF SERVICE**

The undersigned hereby certifies that on March 1, 2017, I caused a copy of the foregoing document **DEFENDANTS MEDICAL COMPONENTS INC. AND MARTECH MEDICAL PRODUCTS, INC.'S RESPONSIVE BRIEF ON CLAIM CONSTRUCTION** to be served via ECF to:

James D. Petruzzi MASON & PETRUZZI 4900 Woodway, Suite 745 Houston, Texas 77056 JPetruzzi@MasonPetruzzi.com

Robert M. Mason MASON & PETRUZZI 13601 Preston Rd. Dallas, Texas 75240 RMason@MasonPetruzzi.com

Alan S. Gold, Esq. Gold and Ferrante, P.C. 261 Old York Road, Suite 526 Jenkintown, PA 19046 asg@goldferrantelaw.com

/s/ Alfred W. Zaher
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